UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/878,034	06/08/2001	Daniel McTeigue	MCP-0279	1620

27777 7590 03/19/2004

PHILIP S. JOHNSON
JOHNSON & JOHNSON
ONE JOHNSON & JOHNSON PLAZA
NEW BRUNSWICK, NJ 08933-7003

EXAMINER	
DI NOLA BARON, LILIANA	
ART UNIT	**PAPER NUMBER**
1615	

DATE MAILED: 03/19/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

UNITED STATES PATENT AND TRADEMARK OFFICE

COMMISSIONER FOR PATENTS
UNITED STATES PATENT AND TRADEMARK OFFICE
P.O. BOX 1450
ALEXANDRIA, VA 22313-1450
www.uspto.gov

BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Paper No. 20040127

Application Number: 09/878,034
Filing Date: June 08, 2001
Appellant(s): MCTEIGUE ET AL.

Sharon E. Hayner
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed November 24, 2003.

(1) Real Party in Interest

A statement identifying the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

A statement identifying the related appeals and interferences which will directly affect or be directly affected by or have a bearing on the decision in the pending appeal is contained in the brief.

(3) Status of Claims

The statement of the status of the claims contained in the brief is correct.

(4) Status of Amendments After Final

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

(5) Summary of Invention

The summary of invention contained in the brief is correct.

(6) Issues

The appellant's statement of the issues in the brief is correct.

(7) Grouping of Claims

Appellant's brief includes a statement that claims 1-9 and 11-24 do not stand or fall together and provides reasons as set forth in 37 CFR 1.192(c)(7) and (c)(8).

(8) Claims Appealed

The copy of the appealed claims contained in the Appendix to the brief is correct.

(9) Prior Art of Record

Morella et al. "Microcapsule Composition and Process" Application for Canadian Patent No. 2,068,366. May 11, 1992.

(10) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-9 and 11-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Canadian Application 2,068,366 to Morella et al.

Morella discloses a taste masked free flowing powder including microcapsules, wherein each microcapsule includes an effective amount of a core element including at least one pharmaceutically active ingredient and a substantially smooth and continuous microcapsule coating on the core element formed from a coating composition including a water-insoluble polymer (See p. 25, claim 1). Morella et al. teaches that this polymer is ethyl cellulose (See p. 25, claim 7). Furthermore, Morella et al. teaches that the active agent can be a non-steroidal anti-inflammatory agent (See p. 25, claim 5). Morella et al. also teaches the taste masked free flowing

powder discussed above, wherein the coating composition includes a water-insoluble polymer (ethyl cellulose) and a polymeric component, which can be an enteric polymer (See p. 26, claim 9). In the disclosure, Morella et al. teaches that enteric polymers include cellulose acetate phthalate, hydroxypropyl methyl cellulose phthalate, hydroxypropyl methyl cellulose acetate succinate and others (See p. 9, lines 30-38). Additionally, Morella et al. teaches that the coating comprises a water-insoluble polymer and one or more of an enteric polymer, an acid-soluble polymer and a partially water-soluble polymer (See p. 26, claim 9). The reference also allows for the inclusion of excipients (See p. 11, lines 23-32). Morella et al. also teaches that the taste masked free flowing powder can be in the form of a chewable tablet (See p. 29, claim 28).

Morella et al. is deficient in the sense that the patent does not teach the particular release profile claimed by Applicant. However, it is the position of the examiner that because Morella et al. teaches the same ingredients as Applicant, it would flow that the invention disclosed by Morella et al. would have the same release profile as the invention claimed by Applicant. The burden is shifted to Applicant to provide evidence that the two compositions exhibit different profiles, if this is the characteristic to be relied upon to show patentable distinction. Absent such an evidence, this invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

(11) Response to Argument

a. Appellant argues that the Canadian Application does not teach or suggest a composition achieving an immediate release dissolution profile, which is an aim of Appellant's invention.

b. Appellant argues that the composition of Example 3 of the Canadian Patent Application provides a release profile, which indicates that less than 80% of the drug is released after 30 minutes in a pH 7.5 solution.

c. Regarding claims 19-24, Appellant argues that Morella et al. does not teach or suggest a combination of water-insoluble film-forming polymers and enteric polymers for masking taste.

d. Appellant argues that the particles disclosed by Morella et al. are prepared by spray drying, which does not produce a "continuous" polymer coating, as claimed in the instant application.

The examiner finds Appellant's argument a, that the Canadian Application does not teach or suggest a composition achieving an immediate release dissolution profile unpersuasive for several reasons. First, the claims in the application do not state that the compositions have immediate release type dissolution profiles. This language is not expressly stated in the claims. Second, the claims are drawn to compositions rather than methods, and therefore Applicant's argument that the aim of the invention is to create immediate release profiles is not persuasive, unless it can be clearly shown that there are differences in the actual composition. The Canadian Application discloses a composition comprising a core and a coating comprising a mixture of an enteric polymer and a water-insoluble film-forming polymer (See p. 4, lines 15-23, p. 8, lines 26-32 and p. 9, lines 19-38). Thus, the composition disclosed by the prior art is the same composition claimed by Applicant. Additionally, the Canadian Application provides the teachings that the amounts of water-insoluble polymer and enteric polymer in the coating may be

varied according to the desired rate of release of the active agent (See p. 8, lines 21-32 and p.10, line 3 to p. 11, line 12). Thus, it would have been obvious to one of ordinary skill in the art to determine the optimal concentration of the water-insoluble polymer and enteric polymer in the coating by routine experimentation, in order to achieve the desired dissolution profile of the active agent in the composition.

In response to Appellant's argument b, that the composition of Example 3 of the Canadian Patent Application provides a release profile, which indicates that less than 80% of the drug is released after 30 minutes in a pH 7.5 solution, the examiner points out that Applicant is testing his dissolution rate at pH 7.2, thus the slight difference in dissolution profiles between Applicant's invention and the invention disclosed by the prior art could be a result of the pH difference. Furthermore, it is noted that the examples in the prior art are the inventor's best mode. It is not necessary for the prior art to disclose Appellant's claimed release profile as best mode, but merely to suggest to one of ordinary skill in the art that the amounts of water-insoluble polymer and enteric polymer in the coating may be varied according to the desired rate of release of the active agent. Thus the skilled artisan would have determined the optimal concentration of the water-insoluble polymer and enteric polymer in the coating by routine experimentation, in order to achieve the desired dissolution profile of the active agent in the composition.

In reply to Appellant's argument c, that Morella et al. does not teach or suggest a combination of water-insoluble film-forming polymers and enteric polymers for masking taste, it is noted that Morella et al. specifically provides a process for preparing a taste-masked powder comprising

providing a coating to a core, wherein said coating comprises a water-insoluble polymer (See p. 12, lines 1-23), and contemplates mixing an enteric polymer with the water-insoluble polymer (See p. 9, lines 19-38).

In response to Appellant's argument d, that the particles disclosed by Morella et al. are prepared by spray drying, which does not produce a "continuous" polymer coating, it is noted that the Canadian Application teaches that controlling process parameters, including temperature, solvent concentration, spray drier capacity and air pressure, allows the formation of a range of coatings, ranging from dense, continuous, non-porous coating, to more porous matrices (See p. 15, lines 20-26). Thus, it would have been obvious to one of ordinary skill in the art to adjust the process parameters, as taught by Morella et al., to obtain a continuous polymer coating.

In conclusion, the examiner maintains that the compositions and methods claimed in claims 1-9 and 11-24 of the instant application are *prima facie* obvious over Morella et al.

For the above reasons, it is believed that the rejection should be sustained.

Respectfully submitted,

Liliana Di Nola-Baron

Patent Examiner

January 27, 2004

THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600

Gollamudi S. Kishore, PhD
Primary Examiner
Group 1600